Committee Expands Ranbaxy Probe to Include PEPFAR Program

Washington, D.C. - Following the Food and Drug Administration’s (FDA) announcement this week that it would partially restrict drug imports manufactured by Ranbaxy Laboratories at two of its India plants, leaders of the Committee on Energy and Commerce have expanded their inquiry into the FDA’s handling of the case to include drugs manufactured by the company for the President’s Emergency Program for AIDS Relief (PEPFAR).

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Ranbaxy
Laboratories is a multinational generic drug firm based in India. For more than three years, the FDA and Department of Justice have been investigating possible fraud and other improprieties in the firm’s applications to sell prescription drugs in the United States.

In
July, Reps. John D. Dingell (D-MI), Chairman of the Committee, and Bart Stupak (D-MI), Chairman of its Subcommittee on Oversight and Investigations, launched an inquiry into whether the FDA knowingly

allowed drugs suspected of being fraudulently approved and manufactured in gross violation of Good Manufacturing Practices (GMP) to continue being sold in the United States.

Today, Reps. Joe Barton (R-TX) and John Shimkus (R-IL), Ranking Members of the Committee and Subcommittee, joined the investigation. The four lawmakers sent a letter to Secretary of State Condoleezza Rice requesting documents relating to the safety and effectiveness of drugs manufactured by Ranbaxy specifically for the PEPFAR program. Allegations have been raised regarding serious irregularities in the application and production process at Ranbaxy.

Drugs for the PEPFAR program are supplied to African and other developing countries to treat HIV/AIDS. The drugs are produced pursuant to “expedited review” by the FDA and paid for with American tax dollars.

These drugs cannot be granted approval for sale in the U.S. because such sales would violate patents. The innovator companies have agreed to license to Ranbaxy and other generic drug firms manufacturing outside the U.S., the right to sell these drugs for use in the PEPFAR program.

“I’m glad Democrats and Republicans are teaming up on this investigation,” said Dingell. “It is important that the recipients of PEPFAR drugs know the FDA has done everything it should be doing to ensure the safety and effectiveness of these life-saving medications.”

“Our bipartisan investigation would not be complete without a close examination of the FDA treatment of PEPFAR drugs produced by Ranbaxy,” said Stupak. “FDA has been charged by the President with assuring that PEPFAR drugs are held to the same standards as drugs headed for American medicine cabinets. This Committee will treat the serious allegations regarding the production and approval of the PEPFAR drugs produced by Ranbaxy as if the drugs were intended for American consumers.”

Read the Letter

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Prepared by the Committee on Energy and Commerce

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